### A. Compound Names

The Examiner has asserted that the names of compounds in certain species claims are inconsistent with the name of the radical (f) in generic Claims 1 and 15. Despite the apparent inconsistency, it is respectfully submitted that all of the names are indeed correct. Enclosed herewith as Exhibit A is a portion of Appendix V (Selection of Index Names for Chemical Substances) from the CHEMICAL ABSTRACTS 1977 Index Guide. The copied portions are Sections 135 and 136, which relate to the naming of compounds of the typed claimed herein.

From the rules presented in the Exhibit, the compounds claimed in the species claims are correctly named as triazoles because the triazole is the parent compound function. The formula for the triazole portion of the compound of Claim 10 (for example) is given below:

Additionally, the radical (f) described in generic Claims 1 and 15 is also correctly named because it is a radical or substituent and not a parent compound function.

Confirmation of the fact that the species claims in question are included within generic Claims 1 and 15 is given by the formulas of the tested compounds shown on the table on pages 35 through 37. The compound of Claim 10, for example, is the second from the bottom on page 37. Comparison of the formula of the radical Y given on page 37 with that in either Claim 1 or Claim 15 will demonstrate that (despite the apparent inconsistency of nomenclature) the compounds themselves are indeed consistent.

It is therefore respectfully requested that this ground of rejection be withdrawn.

# B. The "How Many Different Inventions" Rejection

The Examiner has asserted as a reason for his rejection, apparently under the first or second paragraph of 35 USC 112, that it is not clear how many different inventions under 35 USC 103 are defined by Claims 1 and 15. It is believed that the Examiner advanced this reason in anticipation of the decision in In re Harnisch, 206 USPQ 300 (C.C.P.A. 1980).

It is nevertheless respectfully submitted, however, that this "reason" will not support the Examiner's rejection.

First, the number of "inventions", in the sense of inventions which might be patentable over each other if separately filed, is irrelevant to a rejection under 35 USC 112. The decision of In re Wolfrum and Gold, 179 USPQ 620 (C.C.P.A. 1973) dealt with this precise issue, the Court holding that Section 112 provides no authority for rejecting a claim on the basis that it includes a plurality of inventions. The rejection reversed in Wolfrum is precisely the same as that at issue here; hence the same outcome should result. This outcome is completely consistent with both Section 803 of the Manual of Patent Examining Procedure, Fourth Edition (June 1979) and the decision of In re Weber, et al., 198 USPQ 328 (C.C.P.A. 1978). While the Weber decision involved a rejection under 35 USC 121, the reasoning therein and the revision of Section 803 of the MPEP which was based thereupon are clearly contrary to the present rejection.

It is further respectfully submitted that this state of the law is in no way altered, and is in fact reinforced, by the decision of <u>In re Harnisch</u>. The Court in <u>Harnisch reversed</u> an "Improper Markush" rejection for the reason that all of the

compounds covered by the rejected claims were coumarin compounds useful as dyes. Hence the claimed compounds were considered part of a "single invention so that there is unity of invention as was held to be the case in <a href="Ex parte Brouard">Ex parte Brouard</a>, 201 USPQ 538 (Board of Appeals 1976)." In elucidating a rule to be derived from its decision, the Court implied that an Improper Markush rejection would lie only where <a href="unrelated">unrelated</a> inventions are involved - inventions which are truly independent <a href="and-distinct">and</a> distinct. In the <a href="Harnisch">Harnisch</a> case, the Court held that such inventions were not involved.

It is respectfully submitted that the  $\operatorname{\underline{Harnisch}}$  decision in no way supports the present rejection.

First, the revised Section 803 of the MPEP had not been published at the time of the <u>Harnisch</u> decision. The Court specifically alludes to the fact that former Section 803 had been cancelled from the MPEP. It is therefore respectfully submitted that the Patent and Trademark Office, being bound by revised Section 803 of the MPEP, is compeled to follow that procedure and may not advance a rejection similar to that presently under discussion.

Second, this point aside, the present claims are completely analogous to those in <u>Harnisch</u> in that they do indeed have a "unity of invention" as that term is used in <u>Harnisch</u>. That is, the claims herein cover compounds which belong to a structural subgenus and which have a common utility, just as did the compounds in <u>Harnisch</u>. Since the rejected claims clearly do not cover <u>unrelated</u> inventions, they should be allowed under the rule in <u>Harnisch</u>.

Accordingly, the rejection on this basis should also be withdrawn.

## C. The "Improper Markush" Rejection

The Examiner's statement further in the Official Action that Claims 1 and 15 are rejected as being Improper Markush

claims because they embrace compounds that are unobvious over each other is taken to be a modification of the reason discussed in the previous section and is thus equally untenable. It is also seen to be improper for the following additional reason.

The Examiner has asserted that the standards for determining which compounds are obvious over each other is set forth in MPEP Section 706.03(y), but this section of the MPEP is also not seen to support the present rejection. The Examiner has referred particularly to the first sentence of the third paragraph of this Section, which is reproduced below:

"The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class."

However, in referring to this particular sentence, the Examiner has ignored much of the remainder of the section, including that portion specifically relating to claims as herein in which the Markush expression is applied only to a portion of a chemical compound.

It is respectfully submitted that the portion of Section 706.03(y) referred to by Examiner applies, not to claims such as those rejected herein, but rather to claims in which the Markush group recites individual chemicals and not portions of a chemical molecule. In any case, this section clearly states that the propriety of a grouping in claims as herein is determined by a consideration of a compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression. Hence, it is respectfully submitted that this section requires nothing more than that all of the claimed compounds possess at least one property in common.

The Examiner is also respectfully directed to the reference in Section 706.03(y) to Section 803 for the appropriate practice to follow regarding Markush-type claims. The Examiner's continued refusal to follow this procedure is deemed to be improper.

## D. The "Reasonable Assurance" Rejection

Claims 4, 5, 8, 9, and 10 are directed to species for which test data are provided in the application. Since these species claims were not previously rejected on this ground, it is respectfully submitted that the Examiner does not intend to reject these species claims for this reason.

Moreover, the Examiner agreed during the Interview made of record in the Response filed February 28, 1980, that the utility of Claim 15 is evidenced sufficiently by the presented data to avoid a rejection of this type. This statement was made of record in this Response and has not been challenged by the Examiner in the outstanding rejection. Accordingly, it is respectfully submitted that Claim 15 is not being rejected for this reason. However, in an abundance of caution, arguments will be presented herein regarding the "reasonable assurance" that the compounds claimed in Claims 1 and 15 are operative for the asserted usefulness.

Initially, the Examiner's attention is drawn to the thorough treatment of this issue in an Applicants' Amendment of September 13, 1979 (pages 6 through 8) and Response filed February 28, 1980 (pages 3 and 4). The Examiner is again respectfully requested to provide some reason for doubting the truth of Applicants' disclosure. In the absence of such supporting reasons, it is believed that this rejection is without merit. The support for this rejection relied upon by the Examiner (In re Surrey and MPEP Section 716) have been met in Applicants' responses, but the Examiner has not in any way commented upon these arguments.

The Examiner's reference to MPEP Section 716, far from supporting his position, in fact supports the position of the Applicants. The entire paragraph referring to <u>In re</u>
<u>Quattlebaum</u> is reproduced below:

"Since it is the Examiner's duty to pass upon the operativeness of any invention which he is called upon to examine he is free to express his opinion on that question so long as he gives reasons for his holding with clarity and completeness. Therefore he need not support every rejection on inoperativeness with references, affidavits, or declarations (citation omitted) (emphasis added)."

Applicants have nowhere requested the Examiner to support his rejection on inoperativeness with "references, affidavits or declarations"; they have merely asked for the reasons that are required by this section of the MPEP.

Accordingly, in the absence of any such reasons, it is respectfully submitted that this rejection should be withdrawn.

## E. The Withdrawal of Nonelected Claims

It is respectfully submitted that the withdrawn claims should also be allowed, in view of the allowability of generic Claim 1 which includes all of the compounds and in view of the commensurate nature of the composition claims.

### F. Conclusion

For the above reasons, it is respectfully submitted that Claims 1-16, all the claims in the application, are allowable and such action is earnestly solicited.

If the Examiner adheres to his rejection, entry of this Amendment for purposes of appeal is respectfully requested.

Respectfully submitted,

Geoffrey G. Dellenkaugh Attorney for Applicants Registration No. 26,864

GGD/jt

501 George Street New Brunswick, N.J. 08903 (201) 524-9323 H<sub>2</sub>NC(=NH)NH- [(aminoiminomethyl)amino]

HN=C=N=

(carbonimidoylamino)

135. Indicated hydrogen is a designation comprising a locant followed immediately by an italic capital Hylaced before a ring system name to express the position of each of the saturated atoms necessary for formation of a definable, stable ring system. Thus, Pyrrole always has one saturated atom (an atom not connected to either of its neighbors by a double bond) and, according to the position of this atom, the compound is named as follows:

In the Chemical Substance Index only a single illustrative structural diagram is provided for each ring system, viz., the diagram which shows the saturated center(s) in the lowest-numbered nonangular position(s).

center(s) in the lowest-numbered nonangular position(s).

Tetrahydropyrrole has the trivial name Pyrrolidine: dihydropyrroles are named as derivatives of that pyrrole which has indicated hydrogen at the lowest numbered position consistent with the structure. Other monocyclic hetero systems are named in the same way. Hydrogen on a single ring atom between two bivalent hetero atoms is not indicated in the name.

Examples:

1H-Pyrrole, 2,5-dihydro- (not 2H-Pyrrole, 1,5-dihydro-)

2H-Pyran, tetrahydro- (not 4H-Pyran, tetrahydro-)

The lowest locants for nonangular positions of fused ring systems are normally cited for indicated hydrogen. Example:

Indicated hydrogen is assigned to angular or nonangular positions when needed to accommodate structural features, e.g., a bridge, spiro junction or ring-assembly junction, if that form of the ring system can exist.

Examples:

When a bridge requires hydrogen to be added, but indicated hydrogen of the parent system cannot be used for that purpose, the lowest locant, or a locant to accommodate a principal function, is chosen for the parent ring, and additional indicated hydrogen is cited in the name ahead of the bridge designation. Example:

hydrogen for the bridge cited a . additional indicated hydrogen, to the "added" hydrogen form (see below), 3a(4H),6-Methano....)

2H-2-Benzazepine 2-ethano

1.3.4.5-tetrahydro-

1,4-dihydro-

After structural requirements have been met, indicated hydrogen is chosen accommodate principal functions or (in a cyclic radical) free valencies long as the number of indicated hydrogens cited equals or exceeds the properties of principal groups or free valencies that must be accommodated. For the us, case of a ring which requires a single indicated hydrogen for us existence, single principal function or free valency is accommodated, but a polytunet; compound is named at the ring system with lowest nonangular indicated hydrogen for the principal commodated by the properties of the

Examples:

136. Added hydrogen is hydrogen which is added to a ring system in !! same operation as, but in a position different from, hydrogen added to ac commodate structural features of a ring system, e.g., bridges, or spire ring-assembly junctions, or principal groups of a heading parent, or free vales. of a parent radical, when indicated hydrogen (¶ 135) is either not needed . the ring system itself or cannot be chosen to accommodate them. It diffefrom indicated hydrogen in being expressed as a locant and capital itali. in parentheses immediately following the locant for the principal function other accommodated structural feature, e.g., "2(1H)-." Use of added hydrogen permits expression of a principal function, etc., in a heading parent instaof as a substituent. Thus, I-Naphthalenone cannot exist without parts hydrogenation of the naphthalene ring system; a name such as Naphthale ... 1,2-dihydro-1-oxo- violates the rule that the principal function be expresas a suffix. Therefore, two hydrogen atoms are added in one operation to prothe name 1(2H)-Naphthalenone, in which the "added" (or "extra") hydrog is at the 2-position.

When principal functions or free valencies require added bydrugen, it assigned to the lowest numbered available angular or nonangular position; ... (1211)-Naphthalenone, 3.4-dihydro- (not (1417)-Naphthalenone, 2.3-did, 3.6-2 (14417)-Naphthalenone, 5.5.7.8-tetrahydro-. When the ring system required indicated hydrogen and it cannot be assigned to accommodate a principal group or free radical, it has preference over added hydrogen for lowest locants. Wapter of the properties of

added hydrogen is not cited unless necessary, it being understood that only sufficient hydrogen has been added to accommodate the functions. Examples

4a(2H)-Naphthalenecarboxylic acid. 1.3.4.5-tetrahydro- (a 4a(1H)-isomer cannot aviet)

4.6(1H.5H)-Pyrimidinedione. dihydro-

(3,4-dihydro-2(1H)-quinolinylidene) (not (1.4-dihydro-2(3H)-quinolinylidene))

H-Benz[e]indene-3,5(2H,4H)-dione,3a.9h-dihydro-



2H-Pyran-3(4H)-one, dihydro- (3H-Pyran cannot exist)



9,10-Anthracenedione (not 9,10= (9H,10H)-Anthracenedione)



1H-Benz[e]indene-1,2(3H)-dione (not 3H-Benzlelindene-1,2-dione) (low numbering of indicated hydrogen is observed, even if added hydrogen must then be cited)



(2,3-dihydro-1,4-pyrazinediyl) (not (1,4(2H,3H)-pyrazinediyl))

Added hydrogen cited when hydrogen is required elsewhere for spiro and ring-assembly junctions is assigned (in descending order of preference) (a) to accommodate another spiro or ring-assembly junction, (b) to accommodate principal groups or free valencies, or (c) to lowest-numbered available positions.

137. Numbering of molecular skeletons. Lowest locants for a set of principal groups, substituents, etc., are always preferred. The set, e.g., 7,6,1.2,4, is compared with another (alternative) set, e.g. 2,3.7,8.5, by rearranging them both in ascending numerical sequence: 1,2,4,6,7 and 2,3.5,7,8. The set with the maximum number of lowest locants is preferred (in this case, 1,2,4,6,7).

Example:



Naphthalene, 7-bromo-6-chloro-1,2-di= hydro-4-nitro- (not Naphthalene, 2-bromo-3-chloro-7,8-dihydro-5-nitro-)

Lowest locants for various kinds of structural features in cyclic and acyclic molecular skeletons are assigned, in order, to:

- (a) hetero atoms (except for "a"-named radicals, see §¶ 127, 161);
- (b) indicated hydrogen;
- (c) principal groups or (for radicals) free valencies;

- - (d) multiple bonds: (e) substituent prefixes:
  - (f) the substituent prefix cited earliest in the name.

- CH2 - O - CH2 - CH2 - O - CH2 - CH2 - O - CH2 - CH2 - OH

2.5.8.11-Tetraoxatridecan-13-ol (not

3.6.9.12-Tetraoxatridecan-1-ol)

2H-Pyran-6-carboxylic acid, 3,4-= dihydro- (not 4H-Pyran-2-carboxylic acid, 5,6-dihydro-)

3-Buten-2-one (not 1-Buten-3-one)

(6-chloro-2,5-dioxo-3-cyclohexen-1-yl)

MeCH+CHC=CCF3

2-Hexen-4-yne, 6,6,6-trifluoro- (double bond given preference over triple bond)

2-Azulenecarboxylic acid, 8-hydroxy-4,= 5-dimethyl-



1.3-Benzenediamine, N¹-ethyl-N³.□ N1,4-trimethyl- (not 1,3-Benzene= diamine, N3-ethyl-N1,N1,6trimethyl-; see ¶ 114)



Benzene, 1-bromo-3-nitro- (not Benzene, 3-bromo-1-nitro-)

138. Index name selection. Most organic compounds have names based on molecular skeletons, e.g., Propanoic acid (from propane); 1,3-Dioxan-2-amine (from 1.3-dioxane). Procedures for selecting the preferred name of this kind for index use are described in this section (see also ¶ 105).

Selection of a heading parent name based on a molecular skeleton is made by successive application of the following principles until a decision is reached. (a) Greatest number of the principal chemical functional group.

- (b) Preferred atomic content of the molecular skeleton in accordance with the order of precedence of compound classes (¶ 106). The heading parent should express at least one occurrence of an atom appearing earliest in the following list: N. P. As, Sb, Bi, B. Si, Ge, Sn, Pb, O, S, Se, Te. (This principle is used to decide between a cyclic and an acyclic parent, hut is not applied to choices between "a" names or between ring systems. When acyclic and cyclic skeletons of the same compound class are present, a cyclic parent is preferred.)
- (c) Preferred ring system. The choice between ring systems for use as heading parents is based on the following criteria, applied successively until a decision is reached. The senior ring system should:
  - (1) be a nitrogenous heterocycle;
  - (2) be a heterocycle;
  - (3) contain the largest number of rings;
- (4) be a cyclic system occurring earliest in the following list of systems; spiro, bridged fused, bridged nonfused (Von Baeyer), fused;
  - (5) contain the largest individual ring (applies to fused carbocyclic systems);

combination and subcombination inventions, and the practice relating to an election between independent inventions, for example, an election of species.

# 802.03 Meaning of General Inventive

Rule 13 of the Patent Cooperation Treaty indicates that an application should relate to one invention or to a group of inventions so linked as to form a single general inventive concept. This single general inventive concept under the Patent Cooperation Treaty relating to unity of invention in international applications substantially conforms to the concepts for the restriction practice which has been used in national applications in the Patent and Trademark Office.

All of the sections of this Chapter relate to both national and international applications except sections 804-804.04, 809.02(b), 809.02(c), 809.02(c), 809.04-821, which relate to national applications only, and section 823, which relates to international applications only.

# 803 Restriction-When Proper

Under the statute an application may properly be held to lack unity of invention or be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (§§ 806.04-806.04(j)) or distinct (§§ 806.05-806.05(i)).

If it is demonstrated that two or more claimed inventions have no disclosed relationship ("independent"), restriction should be required. If it is demonstrated that two or more claimed inventions have a disclosed relationship ("dependent"), then a showing of distinctness is required to substantiate a restriction requirement.

Where inventions are neither independent nor distinct, one from the other, or they are not sufficiently different to support more than one patent, their joinder in a single application must be permitted.

### PRACTICE RE MARKUSH-TYPE CLAIMS

The subject matter here has been revised in view of the decisions In re Weber et al., 198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978).

This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. In many cases, the Markush-type claims include independent and distinct inven-

tions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s).

In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. Should the Markush-type claim be found not allowable, examination will be limited to the Markush-type claim to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markushtype claim and claims to the elected species shall he rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markushtype claim with respect to a non-elected species. the Markush-type claim shall be rejected and claims to the non-elected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all non-elected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the

amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim will not be

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serions burden, the examiner is encouraged to examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the above procedure and will not require restriction.

### 803.01 Review by Primary Examiner

Since requirements for restriction under Title 35 U.S.C. 121 are discretionary with the Commissioner, it becomes very important that the practice under this section be carefully administered. Notwithstanding the fact that this section of the statute apparently protects the applicant against the dangers that previously might have resulted from compliance with an improper requirement for restriction, STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION. Therefore to guard against this possibility, the primary examiner must personally review and sign all final requirements for restriction.

### 804 Definition of Double Patenting

Double patenting does not relate to international applications which have not yet entered the national stage in the United States.

There are two types of double patenting rejections. One is the "same invention" type double patenting rejection based on 35 U.S.C. 101 which states in the singular that an inventor "may obtain a patent." This has been interpreted as meaning only one putent.

The other type is the "obviousness" type double patenting rejection which is a judicially created doctrine based on public policy rather than statute and is primarily, intended to prepent prelongation of monopoly by prehibiting claims in a second putent not patentably distinguishing from claims in a first patent. In re White et al., 160 USPQ 417; In re Thorington et al., 163 USPQ 644. Note also §§ 804.01 and

The Court of Customs and Patent Appeals has held that a terminal disclaimer is ineffective in the first type, where it is attempted to

twice claim the same invention. However, the "obviousness" type double patenting rejection may be obviated by a terminal disclaimer.

The term "double patenting" is properly applicable only to cases involving two or more applications and/or patents having the same inventive entity and where an invention claimed in one case is the same as, or not patentably distinct from, an invention already claimed. The term "double patenting" should not be applied to situations involving commonly owned cases of different inventive entities are to be treated in the manner set out in \$804.03.

The inventive entity is the sole inventor or the joint inventors listed on a patent or patent application. A sole inventor in one application and joint inventors in another application cannot constitute a single or the same entity, even if the sole inventor is one of the joint inventors. Likewise, two sets of joint inventors do not constitute a single inventive entity if any individual inventor is included in one set who is not also included in the other set.

## 804.01 Nullification of Double Patenting Rejection

35 U.S.C. 121, third sentence, provides that where the Office requires restriction at the national stage, the patent of either the parent or any divisional application thereof conforming to the requirement cannot be used as a reference against the other. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restriction where the claims define essentially the same inventions in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

The apparent nullification of double patenting as a ground of rejection or invalidity raises many troublesome questions as to meaning and situations where it applies.

- A. SITUATIONS WHERE THE DOUBLE PATENTING PROTECTION UNDER 35 U.S.C. 121 DOES NOT APPLY
- (a) The applicant voluntarily files two or more cases without requirement by the examiner.
- (b) The claims of the different applications or patents are not consonant with the requirement made by the examiner, due to the fact that the claims have been changed in material respects from the claims at the time the requirement was made.